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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/208,629	12/08/1998	SHAUN R. COUGHLIN	06510/060DIV	8370

7590 09/29/2003

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EXAMINER

PAK, MICHAEL D

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 09/29/2003

32

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/208,629

Applicant(s)

COUGHLIN ET AL.

Examiner

Michael Pak

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-8 and 13-15 is/are pending in the application.
- 4a) Of the above claim(s) 13-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5, 8 is/are rejected.
- 7) ☒ Claim(s) 6 and 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3, 5, 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election with traverse of Group I, claims 5-8 in Paper No. 29 is acknowledged. The traversal is on the ground(s) that it would not be unduly burdensome for the examiner to search the claims of Group I in conjunction with the claims of Group II. This is not found persuasive because the groups are classified separately.

The requirement is still deemed proper and is therefore made FINAL.

2. Preliminary amendment filed 24 May 2001 (Paper No. 14) has been entered. Newly amended claims 6-7 have been entered.

Sequence Compliance

3. The reply filed 9 June 2003 (Paper No. 31) is not fully responsive to the communication mailed 9 May 2003 (Paper No. 30) for the reason(s) set forth. The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R.

1.821 - 1.825 for the following reason(s): the claims recite SEQ ID NO:24-28 but neither the paper sequence listing nor the CRF disclose the SEQ ID NO:24-28.

Applicant must provide: A substitute computer readable form (CRF) copy of the "Sequence Listing"; A substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification; and a statement that the content of the paper and computer readable copies are the same and, where applicable, include

Art Unit: 1646

no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 5-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5 and 8 are indefinite and ambiguous because it is not clear what is the metes and bounds of "a protease-activated receptor 3". It is not clear whether the "a protease-activated receptor 3" of the present invention is related to the "a protease-activated receptor 3" with the specifically disclosed SEQ ID NO: or whether the applicants envision a "a protease-activated receptor 3" which has no known relationship to the specifically disclosed SEQ ID NO:. For example it is not clear how to distinguish "a protease-activated receptor 3" from "a protease-activated receptor 4" or "a protease-activated receptor 6".

Claims 6 and 7 are indefinite and ambiguous because the claims recite SEQ ID NO:24-28 but the sequences are not disclosed in the sequence listing.

5. Claims 5 and 8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the disclosed polypeptide comprising the sequence encoding SEQ ID NO:3 or 6, does not reasonably provide the full scope of enablement for a proteinase-activated receptor 3 without a defined structure. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 5 and 8 encompass any protease-activated receptor 3 including those not disclosed in the specification. However, the specification does not teach how to use any protease-activated receptor including those not disclosed and unknown in the art at the time of the invention because the claims are single means claims. A single means claim is a claim which depend on a recited property, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor (MPEP 2164.08(a)). Thus, as defined by the specification "protease-activated receptor 3" encompasses any cell surface protein which is specifically activated by thrombin or a thrombin agonist (pages 6-7). Thus, the claims encompass any proteins which are activated by protease without the requirement for any structural limitations. It would require undue experimentation to identify and use a receptor where the structure and functional mechanism is not known because the one skilled in the art uses method based on identification by expression cloning or PCR cloning based on sequence identity which

Art Unit: 1646

requires the knowledge of receptor structure that are different from the G-protein binding receptor family (Nystedt et al.). Specification fails to teach how to make and use receptors which do not belong to the G-protein binding receptor family. Without such disclosure undue experimentation is required to identify and use PAR3 receptors which are different from the PAR3 receptors disclosed in the specification. Therefore, in view of the large extent and unpredictable nature of the experimentation which would be involved, one skilled in the art could not make and use the full scope of the invention as claimed without undue experimentation.

6. Claims 5 and 8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 5 and 8 encompass protease activated receptor peptide variants and fragments which encompasses a large genus of G-protein receptor. However, the essential feature of the invention is the peptide of SEQ ID NO:3 and 6, and one of skilled in the art cannot envision the full genus of antibodies which bind claimed variant molecules. The claims encompass receptors whose structure is not known or other variant proteins with different function from SEQ ID NO:3 and 6 taught in the specification because the term "comprising" encompass structures which is not part of SEQ ID NO:3 and 6. Claimed receptor encompass a large genus of proteins which

Art Unit: 1646

which are alleles or variants whose function has yet to be identified from different species of animal because the structure of the newly identified naturally occurring protein is not known. *University of California v. Eli Lilly and Co. (CAFC) 43 USPQ2d 1398* held that a generic claim to human or mammalian when only the rat protein sequence was disclosed did not have written description in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 5 and 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Coleman et al. (US 5,686,597).

Coleman et al. disclose a thrombin receptor homolog (TRH; column 3, lines 50-67).

Although TRH is not called a protease activated receptor 3, TRH is encompassed within the family of protease activated receptors because thrombin receptors are protease activated receptors (column 1, lines 10-25) and is not excluded by the definition of "protease activated receptor 3" in the specification on pages 6-7.

8. Claims 1-2 and 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Nystedt et al.(PNAS, 1994).

Nystedt et al. disclose the the protease activated receptor (PAR-2; page 9209, figure 2). Although PAR-2 is not called a protease activated receptor 3, PAR-2 is encompassed within the family of protease activated receptors because the receptor is

Art Unit: 1646

protease activated (page 9211, left column) and is not excluded by the definition of "protease activated receptor 3" in the specification on pages 6-7.

9. No claim is allowed. The prior art references also do not teach SEQ ID NO:3 or 6.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (703) 305-7038. The examiner can normally be reached on Monday through Friday from 8:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Michael Pak

Primary Patent Examiner

Art Unit 1646

26 September 2003